

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- BLURRY OR ILLEGIBLE TEXT
- SKEWED/SLATED IMAGES
- COLORED PHOTOS
- BLACK OR VERY DARK BLACK AND WHITE PHOTOS
- UNDECIPHERABLE GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/32		A1	(11) International Publication Number: WO 98/14125 (43) International Publication Date: 9 April 1998 (09.04.98)
<p>(21) International Application Number: PCT/US97/17426</p> <p>(22) International Filing Date: 26 September 1997 (26.09.97)</p> <p>(30) Priority Data: 08/720,699 2 October 1996 (02.10.96) US</p> <p>(71) Applicant: SPECIALIZED HEALTH PRODUCTS, INC. [US/US]; 655 East Medical Drive, Bountiful, UT 84010 (US).</p> <p>(72) Inventors: THORNE, Gale, H.; 1056 Millcrest Circle, Bountiful, UT 84010 (US). THORNE, Gale, H., Jr.; 1898 South Chokecherry Drive, Bountiful, UT 84010 (US). OWEN, Charles, V.; 10754 North 6000 West, Highland, UT 84003 (US). STOUT, Gary, H.; 1333 North 1700 West, Farmington, UT 84025 (US). FARNES, Tim, L.; 287 North Springridge Drive, North Salt Lake, UT 84054 (US).</p> <p>(74) Agents: EVANS, Paul, S.; 1661 Somerset Court, Farmington, UT 84025 (US) et al.</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(54) Title: LANCET APPARATUS AND METHODS</p> <p>(57) Abstract</p> <p>A one-time-use, self-powered, disposable lancet apparatus (700, 750, 800, 900) packaged both as strips (600) comprising a plurality of lancets (41') and as individually packaged lancets (700, 750, 800, 900). A novel lancet blade design comprises means (515) for attaching each blade (500, 500') in a loader stack for an automated assembly machine. Individually packaged lancets (700, 750, 800, 900) are disclosed in both one-step (750, 800, 900) and two-step (700) embodiments. In each case, every lancet (700, 750, 800, 900) comprises a self-contained package (802) which houses a powered lancet blade (500, 500') before use and a spent blade (500, 500') after use to assure safety from inadvertent sticks both before and after a lancing procedure.</p>	

LANCET APPARATUS AND METHODS**FIELD OF THE INVENTION**

5 This invention relates generally to lancets and more particularly to novel, self-contained, precocked and single-use lancets which, when activated, extend a tip of a lancet blade outward from a lancet housing and back into the housing for safe disposal. In a preferred embodiment, the housing is sealed to maintain sterility of the blade before use. A portion of the housing is preferably frangible, and the portion is
10 franged to initiate a single lancing cycle and to subsequently make the lancet unreusable.

BACKGROUND OF THE INVENTION

In particular, U.S. Patent Number 5,514,152 (Smith), issued May 7, 1996,
15 discloses a lancet having a cocked torsion spring wound about a centrally disposed hub frangibly connected to a lancet housing. Generally, the housing is disclosed to be a container for a plurality of lancets, each of which, after use, is frangibly separated from the rest of the strip and individually discarded. The spring is directly interconnected to a lancet blade in a cam/cam follower relationship. When the hub is
20 frangibly separated from the housing, the cocked spring is released to drive a lancet blade tip linearly from the housing and then return it safely back into the housing.

Smith discloses frangible separation of the hub from the housing where a base of the hub is annularly connected by sharp corners to the housing. It is taught that stress placed upon the base causes the hub to fracture from the housing, permitting the lancing cycle to begin. Of course, before each lancing cycle is initiated, a housing
25

frange sites, which can catch upon other edges of the housing and inadvertently keep the spring from unwinding and preventing the blade from completing a lancing cycle.

5

Accordingly, it is a primary object of the present invention to provide a one-time-use, self-driven lancet having a readily frangible, molded connection between a hub and housing which permits the hub to separate from the housing without extraneous fragments being disposed about the hub where the hub/housing frange is disposed.

10

It is another primary object of the present invention to provide a single, one-time-use lancet embodiment in which a carrier and lancet housing are combined in a single disposable unit.

It is an important object of the present invention to provide an embodiment of the single, one-time-use lancet which operates in two steps, one of which is to break a sterile barrier and the other of which is to initiate a lancet cycle.

15

It is a further object of the present invention to provide an embodiment of the single, one time use lancet which operates in a single step, wherein the breaking of a sterile barrier and initiating of a lancet cycle are performed in a single operating step.

20

It is another object of the present invention to provide an embodiment of the single, one-time-use lancet which operates in the single step of squeezing two displaced, but juxtaposed parts together to perform the two steps of breaking the sterile barrier and initiating the lancet cycle.

It is yet another object of the present invention to provide a lancet blade which is facilely used in automated assembly of a lancet.

Figure 6 is a top elevation of a lancet compartment depicted in Figure 5, showing a fired lancet in mid-cycle wherein a tip of a lancet blade, which is a key part of a lancet assembly, is protruding from the lancet compartment.

5 Figure 7 is similar to Figure 5, but showing a spent lancet with the lancet tip retracted into the lancet compartment.

Figure 8 is a section taken along lines 8-8 in Figure 4; shown without a lancet for clarity of presentation.

Figure 9 is a perspective drawing showing a related art representation of the direction of insertion of a lancet housing into a housing carrier.

10 Figure 10 is a perspective drawing showing the initial position of the lancet housing shown in Figure 9 and properly inserted into the housing carrier.

15 Figure 11 is a perspective drawing of the housing and carrier illustrated in Figure 10, showing the distal end of a lancet compartment newly exposed by frangible separation from a preceding compartment and revealing an exit aperture for a first to-be-used lancet.

Figure 12 is a perspective drawing of the housing and carrier illustrated in Figure 11, showing a used lancet compartment frangibly separated from the remainder of the housing and revealing an exit aperture for a next to-be-used lancet.

20 Figure 13 is a top elevation view of a lancet blade of the present invention.
Figure 14 is a perspective of a plurality of blades affixed to a blade magazine for automatically loading blades into the lancet housings.

Figure 15 is a perspective of a strip of lancets comprising a blank section disposed between each lancet.

DETAILED DESCRIPTION OF THE INVENTION

In this description, the term proximal is used to indicate the segment of a device or other apparatus normally closer to a user when the device is properly used. The term distal refers to a direction which is farther removed from the user than a segment which is proximal. Reference is now made to the embodiments illustrated in Figures 1-28 wherein like numerals are used to designate like parts throughout. In order to properly reference novelty of the instant invention, a summary of a portion of the disclosure found in Smith is provided and referenced as related art.

Reference is made to Figure 1 which shows the inner surface of a lancet assembly member 10 of the preferred embodiment of Smith. Assembly member 10 comprises distal end 20, proximal end 30, and multiple empty housing compartments 40 separated by frangible segments 42 whereat the housing compartments can be easily and manually separated without special tools. Assembly alignment pin holes 44 and 46 are also shown. Construction of each housing compartment 40, which is an integral operating portion of each individual lancet 41, is substantially the same as each of the others. As can be more easily seen in Figure 2, typically each housing compartment 40 comprises a hub 50, a torsion spring anchor slot 62 which is an integral part of hub 50, a lancet blade slide plane 70, guides 80 and 81, and at least one frangible section 90, associated with frangible segment 42. Hub 50, placed substantially in the center of compartment 40, is part of the lancet triggering mechanism disclosed in detail hereafter. Groove 60 across the centerline of hub 50 provides a locking apparatus for that part of a torsion spring which will drive the lancet when the spring is freed to unwind. The torsion spring anchor slot 62 holds a

pressed into groove 60. At the wire end of straight segment 124 the spring is bent vertically upward forming crank arm 126, which is used to form an interlock between torsion spring 110 and a coupling slot 130 of lancet blade 120. Thus, crank arm 126 comprises a cam and arcuate coupling slot 130 comprises a cam follower. The 5 cam/cam follower structure, sometimes referred to as a track structure, provides rotary to linear motion translation.

In Smith, lancet assembly 100 comprises lancet blade 120 which is of unitary, stainless steel construction comprising a very sharp lancet tip 140, torsion spring 110, coupling slot 130, guide edges 132 and 133, and leading edge 134. To complete 10 assembly of lancet bottom housing 10 in a compartment 40, lancet blade slot 130 is placed over the already positioned torsion spring crank arm 126 such that lancet blade 120 lies on slide plane 70 with lancet tip 140 in channel 96 and edges 132 and 133 in line with edge guides 80 and 81.

A top elevation view of lancet bottom housing 10, having a plurality of lancet 15 blades 120 and springs 110 assembled therein, is shown in Figure 4. A housing cover, which normally covers the lancet bottom housing 10, is not shown for clarity of presentation but is described in detail hereafter. Torsion spring 110 is cocked and held firmly in place by a slot 62 and a groove 60. Before lancet blade 120 can be fired, the lancet tip 140 exit aperture 98 is opened by frangibly separating the lancet 20 bottom housing 10 within a frangible area 42.

The lancet is actuated by breaking the attachment of the hub 50 free from the compartment 40. One mode of actuation is best seen in Figure 8, which is a section along lines 8-8 of Figure 4, with lancet blade 120 removed for clarity of presentation.

is precisely determined. The depth of puncture in the currently preferred embodiment is 1.7 to 3.0 millimeters.

Further unwinding of torsion spring 110 continues to drive crank arm 126 in a nearly circular counter clockwise direction causing lancet blade 120 to be retracted as shown in Figure 7, thereby completing translation of torsion spring 110 rotary motion to bi-directional linear travel of lancet blade 120. With a cover in place, lancet compartment 40, now containing a totally retracted spent lancet 120, is a safe disposable. There is no "bounce" or multiple excursion of lancet tip 140 from the housing because the forcing direction of the biasing memory of the torsion spring forces lancet blade 120 away from travel limit edge 94 and egress/ingress port 98.

An enveloping or encapsulating housing cover 150 is shown in Figure 3. Cover 150 is inverted, disposed to cover a bottom 10 after assembly, and permanently affixed thereto by either adhesion, ultrasonic bonding or another plastic adhesion method, such as thermal bonding. Once a spring 110 and a blade 120 are mounted into each lancet compartment 40, cover part 150 is accurately positioned relative to bottom 10 through the use of alignment pins and holes or by ridges and grooves used in ultrasonic bonding to cover every compartment 40. It is important that the strip formed by joining bottom 10 and cover 150 form a hermetically sealed unit which does not require further packaging for transport prior to use.

Smith discloses that both bottom 10 and cover 150 members may be molded from synthetic resinous material such as, but not limited to, polymethylmethacrylate, filled polypropylene, polystyrene, and acrylics. Depending upon the material used,

area surrounding the carrier 400 or carrier 400 itself. It is one of the main objects of this instant invention to prevent that event.

In the following detailed description of the instant invention, items which are similar in form and function to those of the related art described in Smith are 5 commonly denoted by the same reference number primed. As an example, an individual lancet which is similar in form and function, but not entirely identical, to individual lancet 41 is denoted by 41' (see Figure 15).

Attention is drawn to Figure 13 wherein a lancet blade 500 of the instant invention is seen. Blade 500 comprises a slot 130', which is similar in form and function to slot 130, and a sharpened lancing tip 140'. However, blade 500 differs markedly from blade 120 by proximally disposed protrusions 502 and 504 on blade 500. As best seen in Figure 13, blade 500 comprises an edge 506, transversely disposed to the direction of the travel of lancet tip 140' and proximally disposed relative to slot 130'. On one side, edge 506 curves arcuately away from slot 130' at a rounded corner 508 to travel normal to the general direction of slot 130' and then curves inward and then outward to form a bulbous inwardly protruding section 510. Edge 506 then continues outward and forward (distal) to complete an outline of blade 500. On the other side, edge 506 curves similarly, but as a mirror image, arcuately away from slot 130' at a rounded corner 512 to also travel normal to the general direction of slot 130' and then curves inward and then outward to form a second bulbous inwardly protruding section 514. From this point, edge 506 continues to define the entire circumference of blade 500.

franging at segment 606 separates a blank part 604 or 602 from an individual lancet 41' to expose a surface 610 of the individual lancet 41' for a lancing operation (as seen in Figure 16).

It is important to note that the exposed surface 610 resulting from separating a
5 blank part (in Figure 16 the blank part is blank part 604), further exposes a shroud 612
about a slot (not seen, but similar to the slot which forms channel 96, shown in
Figures 5-7 and 11 and 12). Shroud 612 is formed by an arcuate raised section 614 in
an inverted bottom 10' in combination with a planar raised section 616 in an attached
cover 150'. Note that the slopes on exposed face 620, formed in combination by parts
10 of bottom 10' and cover 150', effectively extend shroud distally outward from the rest
of strip 600 to aseptically isolate the skin contacting areas of shroud 612. In this
manner, blood and other material emitted from a lance site is either contained or
effectively isolated from the distal portions of a carrier or other portions of strip 600
to be used later. Note also that shroud 612 comprises a sterile interior face 622 when
15 separated from a blank part 604 or 602. Thus, each subsequent individual lancet 41'
presents a sterile, confined interface to its associated lance site.

Reference is now made to Figure 17, wherein a bottom section 630 of an
individual lancet 41' is seen. Section 630 comprises a hub 50', which is substantially
the same as hub 50 earlier described, and which comprises a groove 60 (substantially
20 the same in form and function to groove 60 earlier disclosed). Further, bottom section
630 comprises an actuator diaphragm 142', which, as is the case of actuator diaphragm
142, is frangibly broken under pressure normal to a surface 632, which is a portion of
diaphragm 142'.

bottom 630 and an associated cover is polystyrene, thirty percent filled with a mineral filler, such as wollastonite. In a currently preferred embodiment, bottom 630 is ultrasonically bonded to a cover. For this purpose, pointed protrusions 642 are molded into the upper segment of bottom 630. Otherwise, lancet cavity 40' is similar in form and function to cavity 40 previously described.

5

10

20

Figure 18 shows a longitudinal section of a portion of a bottom 630 comprising a first disposed blank 604 and a first-to-be-used individual lancet 41'. Dashed line 644 denotes a frange line between blank 604 and individual lancet 41'. Franging along line 644 opens shroud 612, thereby providing an exit and reentry portal for lancet blade 500, not seen in Figure 18 for clarity of presentation. In Figure 18, the disposition of annular groove 634 relative to annular groove 636 is also seen. A next frange line 646, along which individual lancet 41' is broken away from the rest of other unused lancets, is proximally disposed relative to dashed line 644.

Reference is now made to Figures 19 and 20, wherein a single lancet 700 (as opposed to a strip of lancets), is shown. Lancet 700 comprises an outer housing 702 and an inner housing 704. Outer housing 702 is a permanent part of lancet 700 and comprises a shroud portal 706 and an actuator button and lever 708. Further, the outer housing comprises a box-like shape having a superior surface 710, an inferior surface 712, a portal side 714, a closed side 716 and a back side 718. Disposed for slidable insertion of inner housing 704 into outer housing 702, outer housing 702 comprises a fourth side 720 having an opening for slidable movement of inner housing 704.

Inner housing 704 comprises a cavity (not shown) which is referenced hereafter as cavity 41' due to its closeness in form and function with cavity 41'

Reference is now made to Figures 21-28 wherein the parts and perspectives of one-step devices are seen. One step devices are defined as lancets which are prepared for actuation and actuated in a single user movement. In Figures 21 and 22, a lancet 750 in an unused state (Figure 21) and in a spent state (Figure 22) is seen. Note that lancet 750 is similar in form to lancet 700. Lancet 750 comprises an outer housing 752 and an inner housing 754. The major difference, apparent from exterior views of lancets 700 and 750, is the lack of an actuator button and lever 708 on lancet 750.

Actuation of lancet 700 is caused by an internally disposed franging system which fires lancet 750 as inner housing 754 is transposed into outer housing 752. The mode of actuation of lancet 750 is clearly seen in Figure 23. As seen in Figure 23, inner housing 754 comprises a cavity 40', a spring 110, a blade 500, an actuator diaphragm 142" and a hub 50". The diaphragm 142" and hub 50" combination seen in Figure 23 primarily differs from the diaphragm and hub combinations disclosed previously by an outwardly protruding conical hump 756 having a common axis with hub 50". Note that, in line with hump 756, the outer housing 752 comprises an open channel 758. Channel 758 is closed by an inwardly sloping surface 760. Sloping surface 760 is positioned to interact with hump 756 as inner housing 754 is translated into outer housing 752 at the time when portal 722 is approximately medially disposed within shroud portal 706. Inward movement of inner housing 754 ultimately causes surface 760 to collide with hump 756, thereby placing an increasing pressure upon diaphragm 142" until hub 50' is frangibly separated from the diaphragm 142". Note that the slope of surface 760 determines the mechanical advantage and, therefore, the rate of change of force which must be imposed upon inner housing 754

comprises a lancet tip 140' exit and reentry port 812 and a raised shroud 814. In combination, inner housing 806 and outer housing 804 comprise a lancet and lancet activation mechanism similar in form and function to that comprising hump 756 and sloped surface 760, except that the lancet activation mechanism is aligned to operate as outer housing 804 and inner housing 806 are moved relative to each other, with the outer housing 804 moving away from a lance site.

Outer housing 804 comprises a rim 816, which provides a housing 804

retarding part which permits outer housing 804 to be retracted from the lance site as plunger 808 is moved relative to outer housing toward the lance site to actuate lancet

800. The state of lancet 800 following a lancing procedure is seen in Figure 26.

A lancet 900 comprising an additional mechanical advantage that provides an additional force to frange a hub 50" is seen in Figures 27 and 28. Similar to lancets

750, 800 and 850, lancet 900 comprises an outer housing 902 and an inner housing 904 which act as inner housing 904 is moved relative to outer housing 902 to actuate the lancet. The source of the mechanical advantage is a pivot pin 906 medially and proximally disposed relative to a lancet blade 500', disposed within inner housing 902.

Outer housing 902 further comprises a curved surface and associated part 908 which is juxtaposed to a lance site during a lancing procedure. Part 908 comprises a lancet tip exit and reentry portal 910, which also acts as a shroud. Outer housing 902 also comprises an opening 912, which permits a portion 914 of inner housing 904 to be slidably translated during activation of lancet 900.

Inner housing 904 comprises a lancet compartment 40", which is similar to cavity 40'. Inside compartment 40", inner housing 904 comprises a hub 50", a spring

disposed upon blade 500'. The medial position is particularly important in a device which rotates about a pivot pin as lancet 900 does.

It is currently preferred that materials used for lancets 700, 750, 800, and 900 are the same as those listed for lancet strip 600.

5

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

10

What is claimed is:

lancet housing which frange when the base of the hub is placed under stress and separated from the rest of the lancet housing are disposed.

2. A one-time-use, disposable lancet actuating apparatus according to
5 Claim 1, wherein said lancet housing comprises an orifice through which the lancet tips travels outwardly and inwardly.

3. A one-time-use, disposable lancet actuating apparatus according to
Claim 2, wherein said lancet housing further comprises a shroud disposed about said
10 orifice, said shroud comprising a raised surface which acts to contain flow of fluid
resulting from action of the lancet.

4. A one-time-use, disposable lancet actuating apparatus according to
Claim 1, wherein said lancet housing comprises a linear strip comprising a plurality of
15 frangibly connected lancet devices.

5. A one-time-use, disposable lancet actuating apparatus according to
Claim 1, wherein said lancet housing comprises only a single lancet device.

20 6. A one-time-use, disposable lancet actuating apparatus according to
Claim 1, wherein said apparatus comprises two housing parts, said lancet housing and
a second housing, said lancet housing disposed as an inner housing slidably disposed
inside said second housing, said lancet and second housings being moved one relative

11. A blade according to Claim 9, further comprising edges formed by coining.

12. A method for operating a one-time-use, disposable lancet comprising
5 an outer housing, an inner housing comprising a self-powered lancet apparatus and an exit orifice from which a lancet blade tip is driven outwardly to lance and then retracted inwardly for safe storage thereafter, and a frangible sealed connection between the outer housing and inner housing, for the purpose of maintaining sterility of the lancet blade tip, comprising the steps of:

10 placing the exit orifice against a surface to be lanced;
moving the outer housing relative to the inner housing to frangibly break the sealed connection; and
triggering the self-powered lancet apparatus to cause the lancet tip to be driven outwardly through the orifice and then inwardly through the orifice.

15 13. A method according to Claim 12, wherein the moving step and triggering step comprise a single continuous motion.

20 14. A method according to Claim 12, wherein the triggering step comprises a motion transverse to the motion of the moving step.

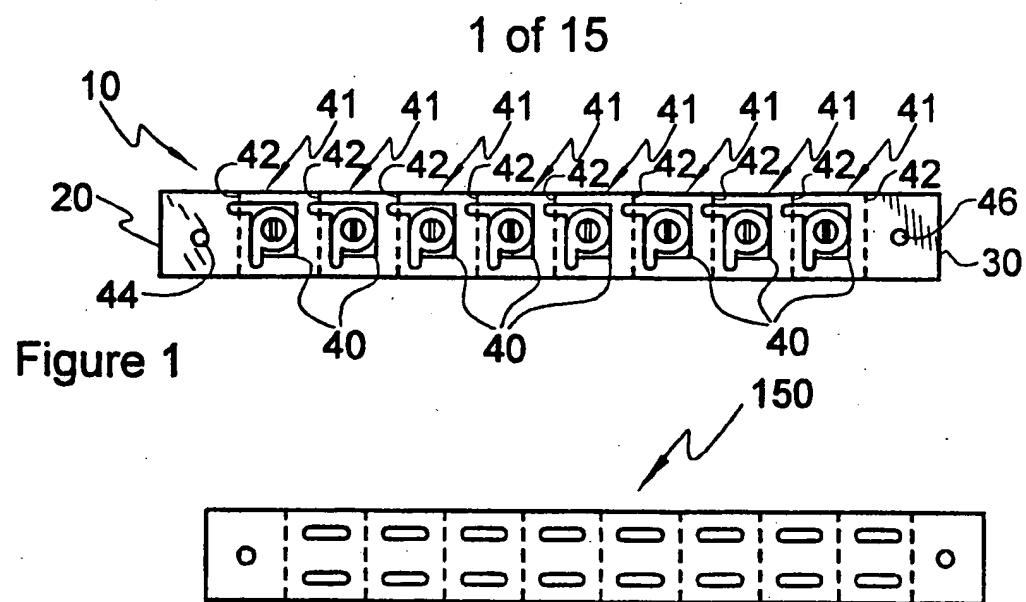
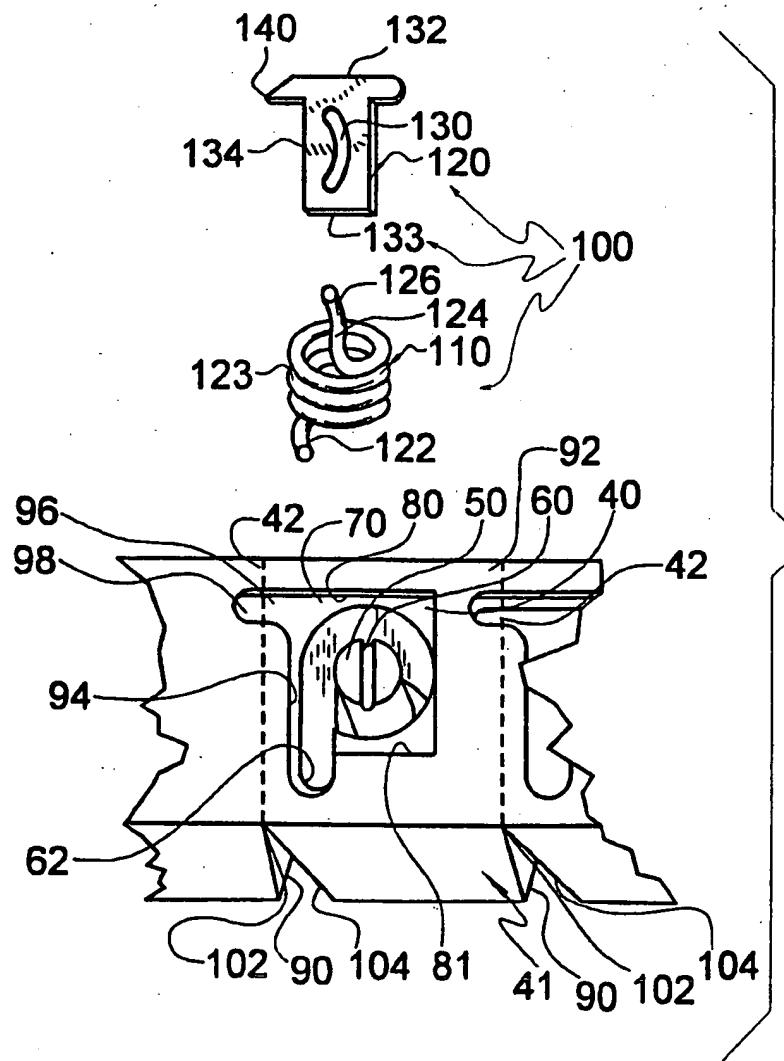


Figure 3



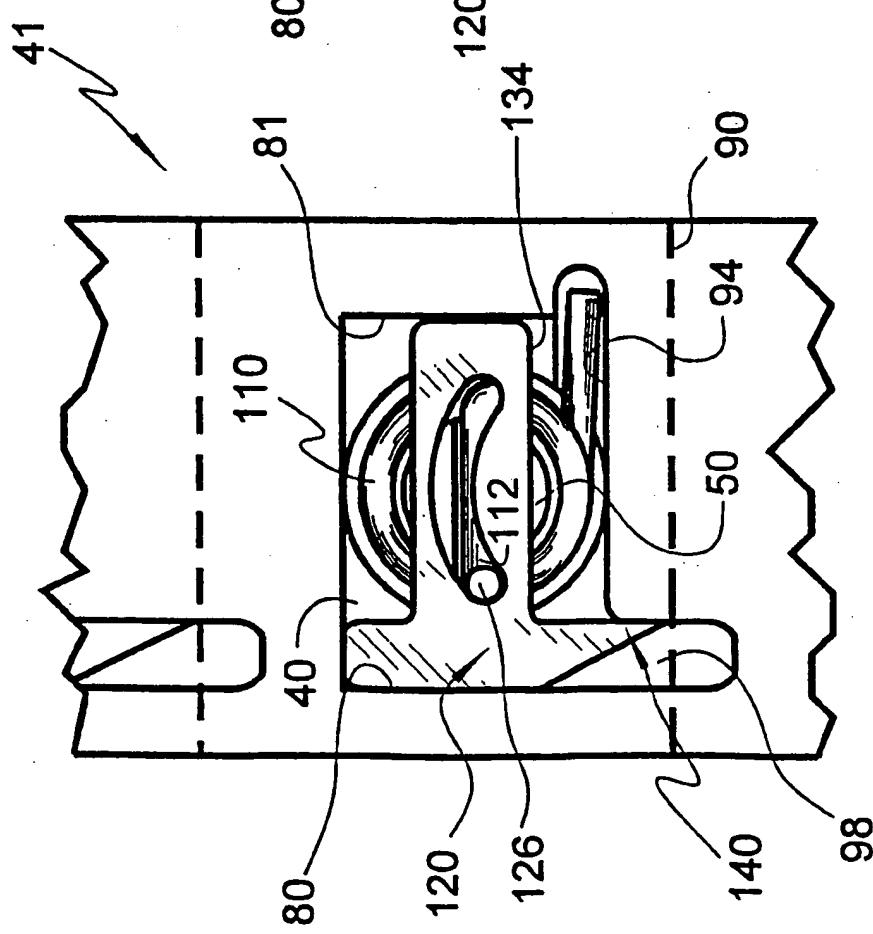
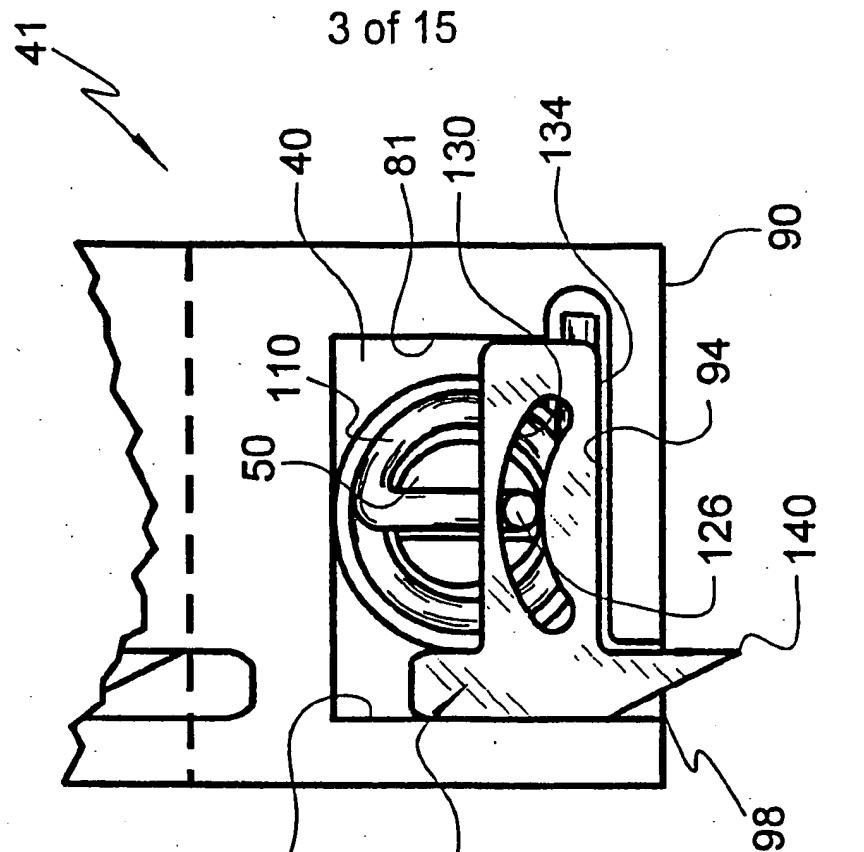
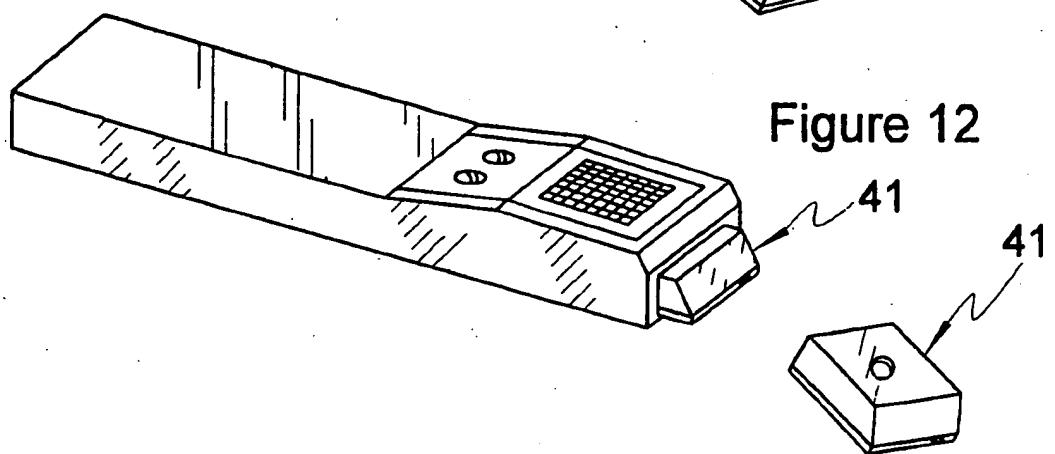
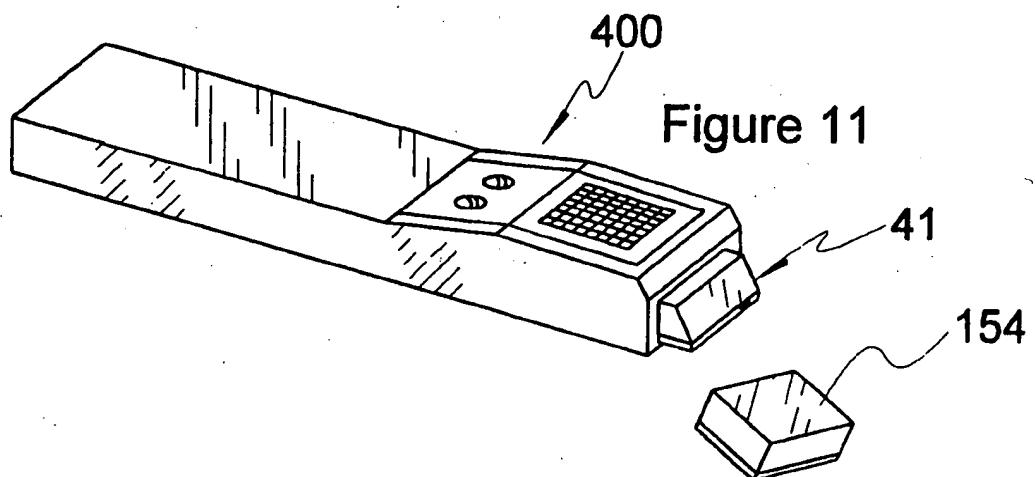
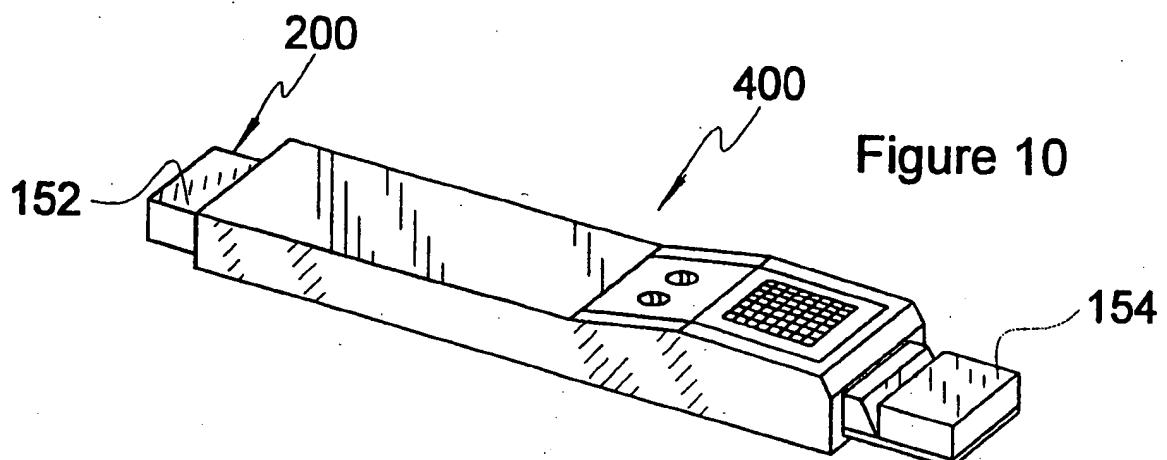


Figure 6

Figure 5

5 of 15



7 of 15

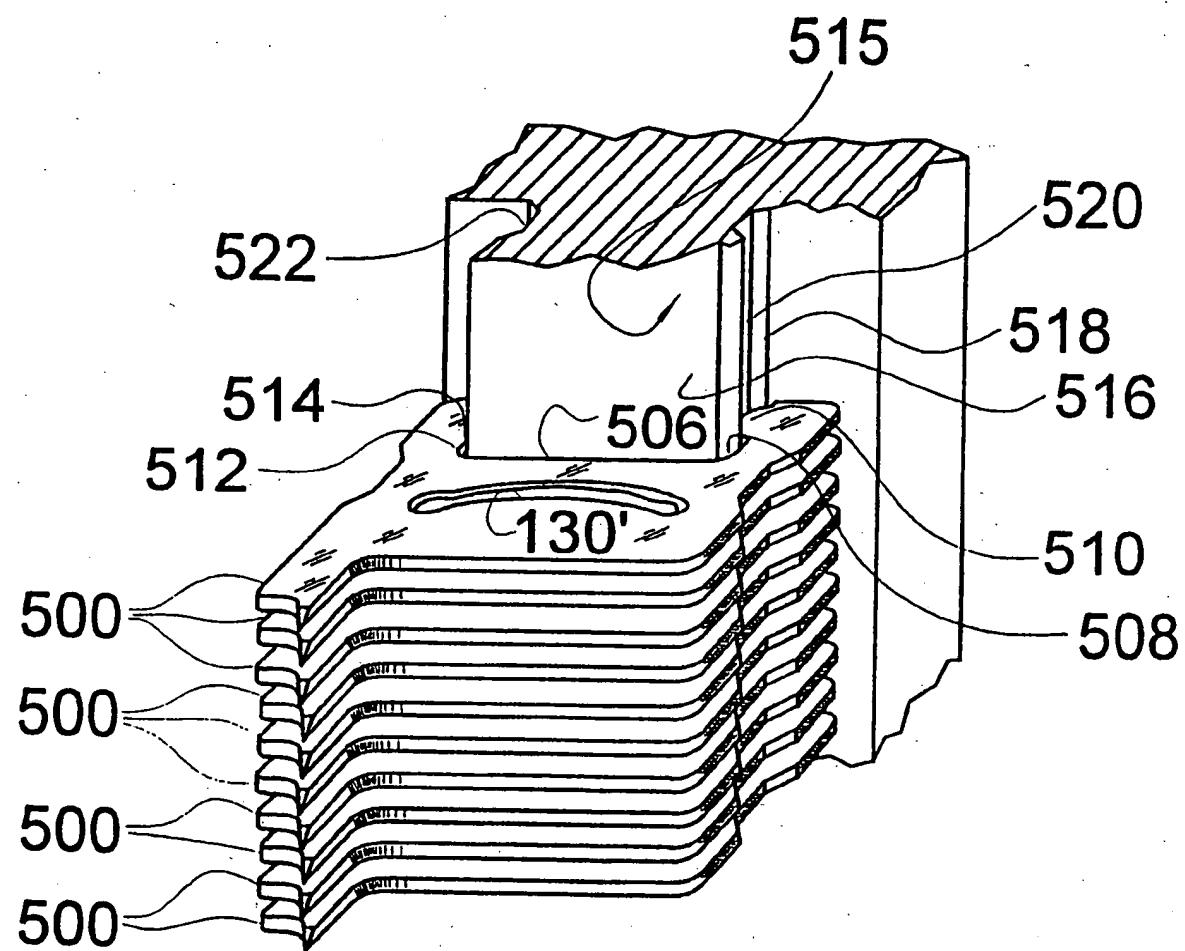


Figure 14

9 of 15

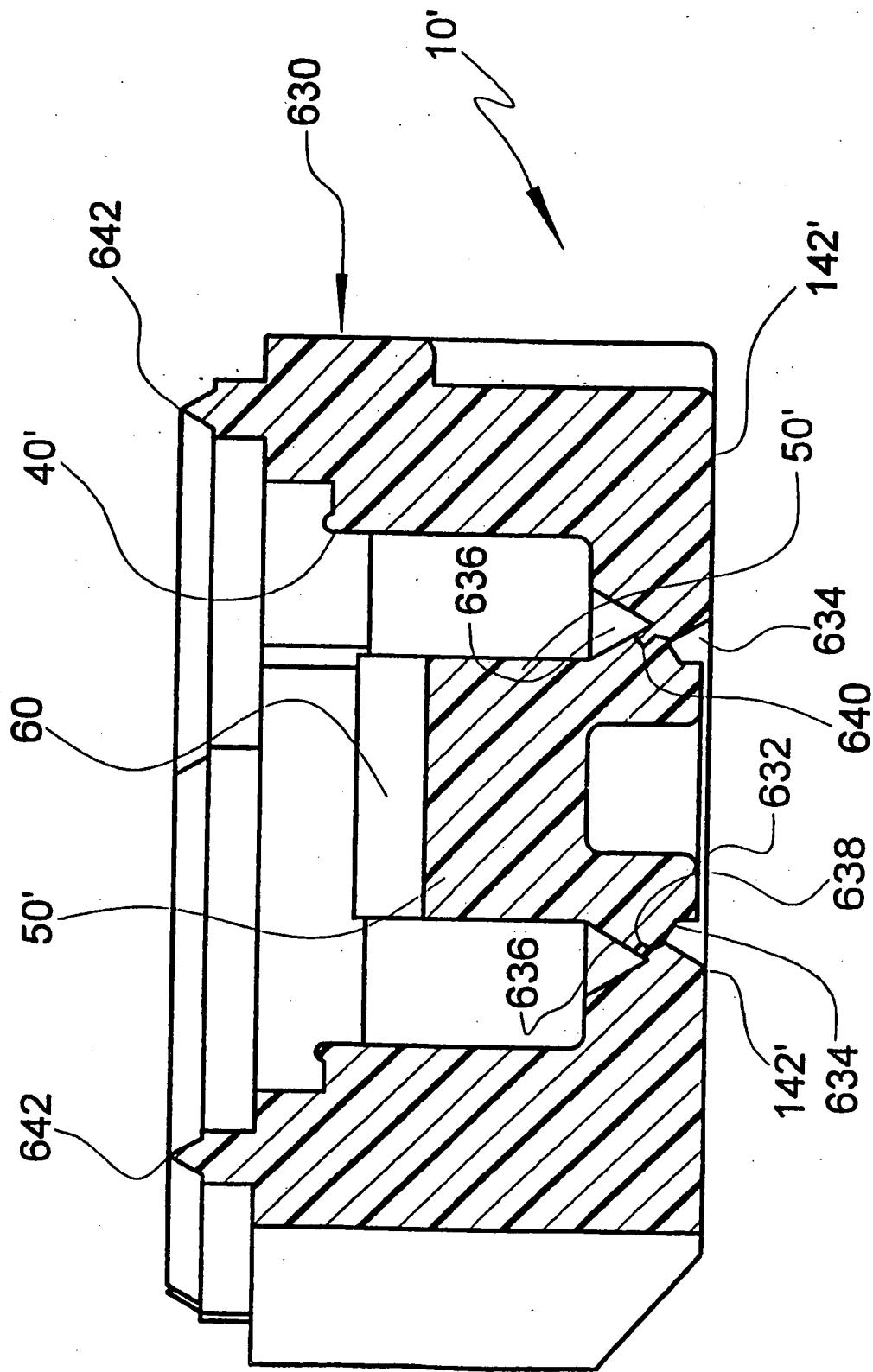


Figure 17

11 of 15

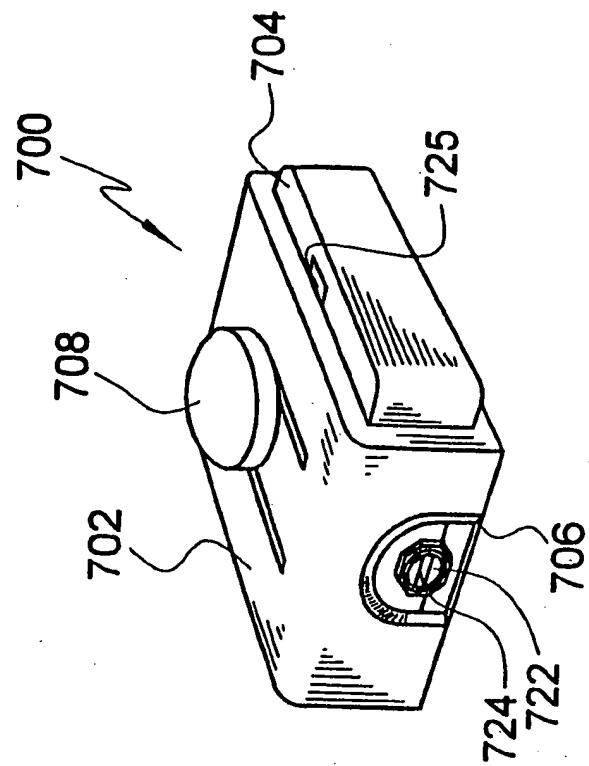


Figure 20

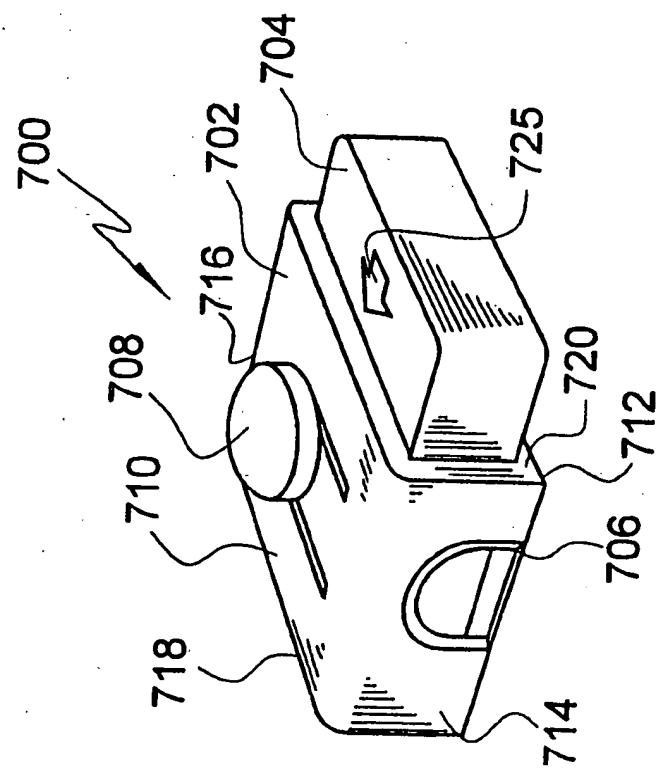


Figure 19

13 of 15

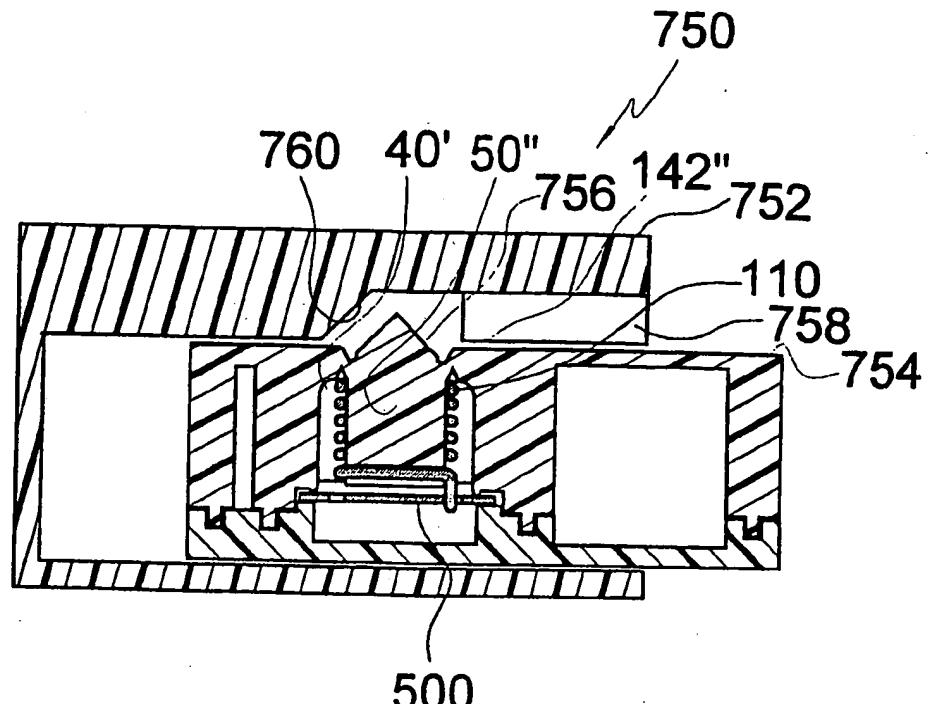


Figure 23

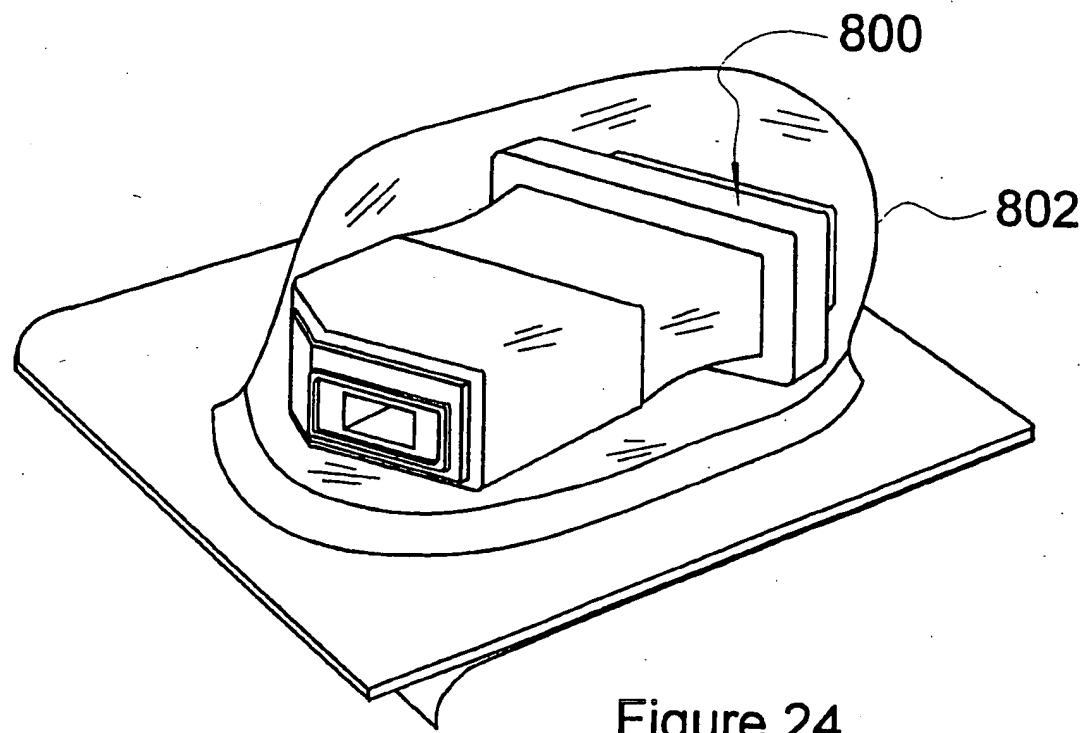


Figure 24

15 of 15

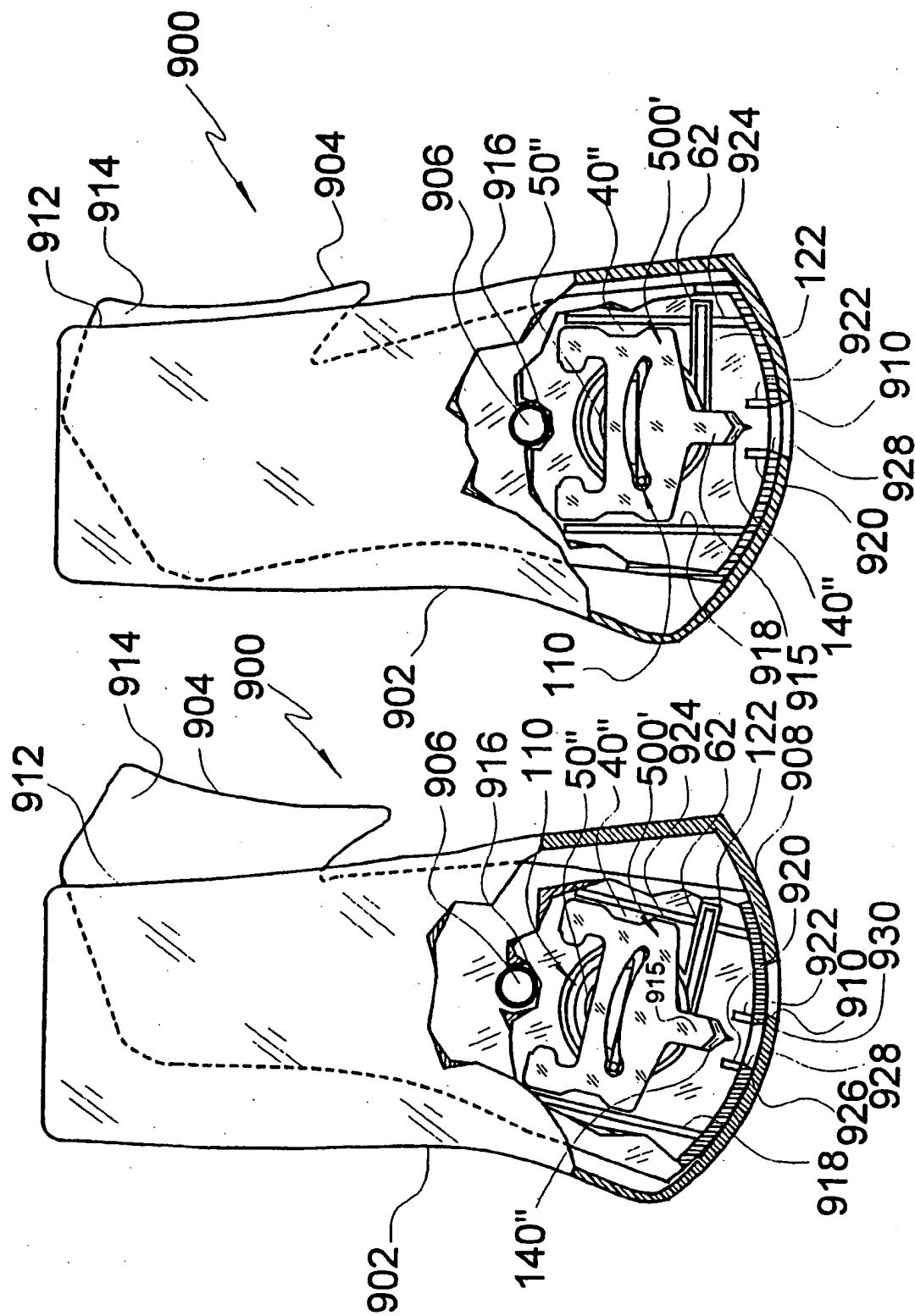


Figure 27

Figure 28

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/17426

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1-8, drawn to a lancet apparatus.

Group II, claims 9-11, drawn to a blade.

Group III, claims 12-17, drawn to a method for lanceting a surface.

Groups I, II and III, the inventions listed as these groups do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group III, the specifics of the blade are not necessary for the lancet or its use. The blade is not claimed as reliable upon use of the lancet in combination therewith. The lancet as claimed need not be used by the method in this group.